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DOCKET NO.: P0453.70113US03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Foss et al.  
Serial No.: 10/785,320  
Confirmation No.: 9706  
Filed: February 24, 2004  
For: ORAL USE OF METHYLNALTREXONE AND RELATED COMPOUNDS  
TO INDUCE LAXATION IN CHRONIC OPIOID USERS

Examiner: Not Yet Assigned  
Art Unit: 1614

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 10<sup>th</sup> day of December, 2004.

Kristin J. Ketelhut  
Kristin J. Ketelhut

MAIL STOP AMENDMENT

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Foss et al., Applicant*

By:

Edward R. Gates  
Edward R. Gates, Reg. No. 31,616  
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600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: P0453.70113US03

Date: December 10, 2004

xNDDx



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Kristin J. Ketelhut  
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**MAIL STOP AMENDMENT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF**  
**DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART III: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding International or Foreign National Application.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Communication</u>
P0453.70112WO00	PCT/US2004/010996	16 August 2004	International Search Report and Written Opinion
P0453.70115WO00	PCT/US2004/010997	31 August 2004	International Search Report and Written Opinion
P0453.70116WO00	PCT/US2004/010998	1 September 2004	International Search Report and Written Opinion

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

Serial No.: 10/785,320  
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Art Unit: 1614

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

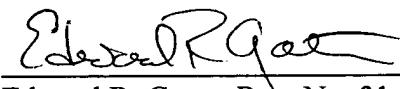
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*Foss et al., Applicant*

By:

  
Edward R. Gates, Reg. No. 31,616  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: P0453.70113US03  
Date: December 10, 2004  
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<b>FORM PTO-1449/A and B (Modified)</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/785,320	ATTY. DOCKET NO.: P0453.70113US03
				FILING DATE: February 24, 2004	CONFIRMATION NO.: 9706
				APPLICANT: Foss et al.	
				GROUP ART UNIT: 1614	EXAMINER: Not Yet Assigned
Sheet 1 of 1					

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
OITE	A55	5,804,595		Portoghesi, et al.	09-08-1998
	856	5,866,154		Bahal, et al.	02-02-1999
DEC 13 2004	A57	2003-0022909	A1	Moss, et al.	01-30-2003
	A58	2003-0124086	A1	Bentley, et al.	07-03-2003
	A59	2003-0191147	A1	Sherman, et al.	10-09-2003

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B28	CA	2,064,373		Lilly (Eli) and Company	09-30-1992	
	B29	EP	506,468	A1	Eli Lilly and Company	09-30-1992	
	B30	EP	643,967	A2	Euro Celtique S.A.	03-22-1995	
	B31	WO	01/32180	A2	Rodeva Limited	05-10-2001	
	B32	WO	02/098422	A1	University of Chicago	12-12-2002	
	B33	WO	03/032990	A2	Shearwater Corporation	04-24-2003	
	B34	WO	2004/014291	A2	Moss	02-19-2004	

#### OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C148	FARTHING et al., New drugs in the management of the irritable bowel syndrome. Drugs. 1998 Jul;56(1):11-21. Review.	
	C149	FINGL et al., Chapter 43: Laxatives and cathartics. In Pharmacological Basis of Therapeutics. 1980: 1002-5.	
	C150	SCHUBERT-ZSILAVECZ et al., Das reizdarmsyndrom irritable bowel syndrome. Deutsche apotheker zeitung. 2002 Aug 22; 142(34): 40-9.	Yes
	C151	TALLEY et al., Pharmacologic therapy for the irritable bowel syndrome. Am J Gastroenterol. 2003 Apr;98(4):750-8. Review.	
	C152	THOMPSON et al., Laxatives: clinical pharmacology and rational use. Drugs. 1980 Jan;19(1):49-58. Review.	

EXAMINER:	DATE CONSIDERED:
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_, filed \_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]